

REMARKS

In the Office Action mailed November 4, 2003, claims 51-94, 96-98, 101-105, and 107 were pending for consideration. The Examiner has rejected claims 51-94, 96-98, 101-105, and 107 on various statutory grounds. Claims 51, 56, 58-60, 65, 70-71, 73-75, 80, 84-85, 87-89, and 102 have been amended. Accordingly, claims 51-94, 96-98, 101-105, and 107 are still pending.

Reconsideration of the application is respectfully requested in view of the amendment and the following responsive remarks. For the Examiner's convenience and reference, the Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

In the Office Action, the following rejections were made:

- (a) claims 51-93 were rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent No. 4,837,381 to Steber et al. (hereinafter "Steber"); and
- (b) claims 51-94, 96-98, 101-105 and 107 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,494,681 to Cuca et al. (hereinafter "Cuca").

REJECTIONS UNDER 35 U.S.C. 103(a)

Before discussing the obviousness rejections herein, it is thought proper to briefly state certain relevant requirements to sustain such a rejection. The issue under § 103 is whether the PTO has stated a case of *prima facie* obviousness. According to the MPEP § 2142, the Examiner has the burden and must establish a case of *prima facie* obviousness by showing some motivation in a prior art reference to modify that reference to teach all the claim limitations in the instant application. The Applicants respectfully assert the Examiner has not satisfied the requirement for establishing a case of *prima facie* obviousness in these rejections.

Rejections over Steber

The Examiner has rejected claims 51-93 under 35 U.S.C. 103(a) as being unpatentable over Steber. The Applicant respectfully asserts the Examiner did not fully consider the Applicant's previous arguments. Additionally, the Applicant has amended independent claims 51, 65, and 80, thereby rendering the Examiner's rejections moot. Accordingly, the Applicant respectfully requests the Examiner to fully reconsider the application in light of the amendments and the remarks contained herein.

Steber teaches slow release compositions of fat or wax having melting points higher than 40°C with an active material, which can be combined to form microspheres (col. 2, ln. 15-59). Also, Steber teaches processes for making such compositions by mixing an active ingredient and other excipients with molten fat, wax or mixture thereof "and then forming microspheres of the resulting mixture by a variety of techniques such as emulsifying or atomizing the mixture or by processing the mixture of ingredients and molten fat, wax or mixture thereof mechanically and cooling, for example utilizing a centrifugal disc" (col. 5, ln. 35-40). The only exemplification of a process for making the microspheres from a mixture is found in Example 1, which states the mixture is homogenous (col. 6, ln. 8-9). The example teaches that the homogenous mixture is "sprayed through an air/liquid spray nozzle," where the air/liquid spray nozzle is equipped with a "heated jacket to maintain the incoming air and the molten phase at a temperature above the melting point" (col. 6, ln 8-14). Further, the example specifically

states "the microspheres are formed as the molten droplets cool and are collected on a series of sieves in the desired size range of about 45 to 180 microns" (col. 6, ln. 8-17). However, Steber does not teach a microencapsulation process, a high shear mixer, mixing in a high shear mixer until microencapsulated particles are formed, or discharging microencapsulated particles as a powder from the high shear mixer. More specifically, the present invention is drawn to a microencapsulation process. The process requires mixing the core material and the oil until microencapsulated particles are formed in the high shear mixer. Also, the process requires discharging the microencapsulated particles as a powder from the high shear mixer. Accordingly, the presently claimed process requires the use of a high shear mixer. A high shear mixer is known generally in the art to include mixers that produce unique mixing action. For example, the unique mixing action can be accomplished by a horizontal shaft which revolves at a high rate of speed, rapidly projecting and hurling the mix materials away from the vessel wall into free space, filling the entire vessel. This type of mixing action can cause the materials to crisscross in the direction of the vessel walls and inversely back again, providing a high volume rate of material transfer throughout the entire length of the vessel. Speeds of these mixers can be from 600 to 2000 RPMs, which are much higher than typical mixers, as claimed in claim 80. Support for the use of a high shear mixer can be found on pages 6-7, and 13-14 of the specification as originally filed.

No Case of *Prima Facie* Obviousness

The applicant respectfully asserts the Examiner's modification of Steber does not satisfy the requirements for establishing a case of *prima facie* obviousness because the reference does not itself provide the motivation for the proposed modification. Steber only teaches forming homogeneous mixtures that undergo a process such as spraying to form microspheres. On the other hand, Steber is completely devoid of teaching that a core material and an oil can be mixed within a high shear mixer to form microencapsulated particles therein. Accordingly, one of ordinary skill in the art would not be motivated to modify Steber to arrive at the instantly claimed invention.

In the recent Office Action, the Examiner stated, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Steber et al. to device processes for the encapsulation of biological material" (pg. 4). However, the Examiner has not indicated how this is obvious. The Examiner may have inadvertently misread Steber, which can be identified by the following quote from the Examiner in the Office Action on page 3:

The preparation of microspheres in Example 1, #2, is performed by mixing the active ingredient with the fat, wax or mixtures thereof, spraying the mixture through a spray nozzle equipped with a heating jacket and cooling the formed microspheres. Thus, the process disclosed by Steber et al. comprises adding a core material and an oil into a mixer, mixing them until microencapsulated particles are formed and discharging the particles, as claimed.

However, Steber specifically states, "the mixture is sprayed", and "the microspheres are formed as the molten droplets cool" and are collected on a series of sieves" (col. 6, ln. 11-16). According to a plain reading of Steber, the microspheres are formed as the molten droplets cool. These molten droplets are a direct result from the spray because molten droplets, by definition, cannot be part of a bulk mixture. If the droplets were part of the bulk mixture, then they could not be droplets at all. Under the teachings of Steber, one of ordinary skill in the art would know that the droplets are formed after the bulk mixture is sprayed through the nozzle. Accordingly, there is no indication from Steber of mixing until microencapsulated particles are formed as asserted by the Examiner. Therefore, Steber is completely devoid of disclosing this teaching, and further lacks any motivation for making such a modification.

Additionally, from the above quotation, the Examiner asserts Steber teaches that the particles are discharged, as claimed. Contrarily, Steber states that the "mixture is sprayed," and the "microspheres are formed as the molten drops cool." Accordingly, there cannot be any discharging of particles. Steber specifically states the mixture is sprayed, which indicates that the bulk mixture in droplet form, not microencapsulated particles, is discharged from the nozzle. Therefore, Steber neither discloses a step of

discharging microencapsulated particles, nor contains any motivation for making such a modification.

Further, Steber is completely devoid of teaching anything about powders in the mixing apparatus. Therefore, Steber lacks any teaching that the microencapsulated particles discharged from a high shear mixer can be a powder as instantly claimed

Furthermore, Steber does not provide any motivation to make a modification of its teachings to arrive at adding a core material and an oil into a high shear mixer, and mixing until microencapsulated particles are formed in the high shear mixer.

Specifically, high shear mixers have been described in the instant application on pages 6-7, and 13-14 as set forth above. Accordingly, the Applicant respectfully asserts that these high shear mixers are separate and distinct from common mixers. While Steber does describe a process of preparing a mixture, it is completely devoid of using a high shear mixer in the preparation thereof. Additionally, there is not a single indication within Steber that a high shear mixer could be used or would be appropriate. Further, while Steber teaches a mixture, nothing indicates mixing until microencapsulated particles are formed in a high shear mixer. Therefore, the only way to read the use of a high shear mixer into the teachings of Steber is by a modification of its teachings. However, there is no motivation arising from Steber to make this modification.

According to the above remarks, nothing in Steber supports the Examiner's obviousness-type rejections to claims 51-93. Steber is devoid of any motivation for making the modifications required to arrive at the instant claims. Thus, the Examiner has not established a case of *prima facie* obviousness, and the Applicant respectfully requests withdrawal of these rejections.

Rejections over Cuca

The Examiner has rejected claims 51-94, 96-98, 101-105 and 107 under 35 U.S.C. 103(a) as being unpatentable over Cuca. The Applicant respectfully disagrees with the Examiner's characterization of Cuca because it does not teach what the Examiner says it does. Additionally, the Applicant has amended claims 51, 65, 80, and 102, thereby

rendering the Examiner's rejections moot. Accordingly, reconsideration of the instant claims and withdrawal of these rejections is respectfully requested.

Cuca teaches a process of melting wax, a hydrophobic polymer, and an active ingredient to prepare a tasteless pharmaceutical delivery system (abstract), where the delivery system can be particles, granulars, slabs, and blocks (col. 2, ln. 47-60, and Examples 1-7). These components can be mixed by stirring, and in "most cases it is necessary to use a high speed mixer and sometimes a colloid mill to obtain a smooth suspension, free of agglomerates" (col. 6, ln. 17-20). Cuca also teaches that after the smooth suspension is obtained, it can be processed depending on the desired type of delivery system (col. 6-20-26). Cuca teaches that after the smooth suspension is made it can be further processed into solid particles by "solidifying the mass while spray or spin congealing the molten material to form particles" (col. 6, ln. 40-45). Additionally, Cuca specifically teaches that "the presence of the hydrophobic polymer material is required to create a tastemasked system," which is the purpose of the disclosed tasteless pharmaceutical delivery system (col. 8, ln. 28-30). However, Cuca does not teach a microencapsulation process, mixing in a high shear mixer until microencapsulated particles are formed, or discharging microencapsulated particles as a powder from the high shear mixer.

No Case of *Prima Facie* Obviousness

In accordance with the Steber analysis, the applicant again respectfully asserts the Examiner's modification of Cuca does not establish a case of *prima facie* obviousness. Cuca neither teaches each and every claim element, nor provides any motivation for modifications thereto for arriving at the claimed invention. While Cuca does teach a method for making particles, it is substantially different from that which is claimed. Accordingly, Cuca is completely devoid of teaching that microencapsulated particles can be formed in a high shear mixer by mixing a core material and an oil therein. Accordingly, one of ordinary skill in the art would not be motivated to modify Cuca to arrive at the instantly claimed invention.

Again, from the Examiner's analysis, the Examiner states that Cuca teaches, "solidifying the mixture to form particles while spin congealing, wherein a high speed mixer is used," and cites col. 6, lines 17-30. However, within Cuca, spin congealing and the use of high speed mixers are used in mutually exclusive steps. Cuca specifically states, "in most cases it is necessary to use a high speed mixer and sometimes a colloid mill to obtain a smooth suspension, free of agglomerates" (col. 6, ln. 18-20). A smooth suspension is not a powder. Further, one of ordinary skill in the art knows that congealing is different than making a smooth suspension. Congealing is a process of solidifying, whereas a suspension is obtained from microscopically visible particles that are dispersed throughout a less dense liquid or gas. Accordingly, Cuca does not teach a high speed mixer for spin congealing as indicated by the Examiner.

The Examiner has also stated, "in the method disclosed by Cuca et al. the particles are formed while the ingredients are mixed" (pg. 5). However, Cuca teaches that after the smooth suspension is obtained, "solidifying the mass while spray or spin congealing the molten material to form particles" (col. 6, ln. 41-43) can be carried out. This is the only place within the entire disclosure of Cuca that teaches how to make particles. While Cuca explicitly identified mixing for formation of the smooth suspension, the process for particle formation is not mixing, but spin congealing and spraying. If Cuca was teaching that mixing formed the particles, the disclosure would have used different mixing terminology, such as that previously used in relation to obtaining a smooth suspension. Cuca did not use such language, as mixing to form a smooth suspension is completely different from spin congealing or spraying to form solid particles. Accordingly, Cuca does not teach that mixing forms particles anywhere.

Additionally, Cuca does not provide any motivation to make modifications to the teachings therein to arrive at these assertions made by the Examiner. While Cuca does include the terms "high speed mixer" and "particles," mixing is not taught to form the particles. Further, Cuca is devoid of anything that would lead one of ordinary skill in the art to modify the teachings and arrive at the Examiner's proposed modifications. Furthermore, Cuca does not teach anything related to discharging the microencapsulated particles as a powder from the high shear mixer. Specifically, Cuca does not teach

anything about the formation of powders, or that the particles can be powders. Accordingly, this is another element of the instant claims that is not taught. There is nothing in Cuca to provide the motivation for making such a modification.

Since Cuca does not teach that microencapsulated particles are formed in a high speed mixer, it lacks disclosure of an element of the instantly claimed invention. Also, by not teaching the element of discharging the microencapsulated particles as a powder from the high shear mixer, it lacks an additional element of the claimed invention. By not providing any motivation therein, it is improper to modify Cuca as the Examiner has proposed to arrive at the instant invention. Therefore, a case of *prima facie* obviousness cannot be maintained. Thus, the Applicant respectfully requests withdrawal of these rejections.

Cuca Teaches Away from the Claimed Invention

Furthermore, instant claims 94, 96-98, 101-105 and 107 are drawn to a composition of microencapsulated particles for oral administration. With respect to these claims, the Applicant asserts that Cuca teaches away from the claimed invention. The Courts have stated that when a prior art reference is used to support claim rejections, the reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1993), *cert. denied*, 469 U.S. 851 (1984). Accordingly, when Cuca explicitly requires a component to be contained within the taught composition, and that component is excluded by the instant claims, Cuca actually teaches away from the claimed invention.

Claim 94 specifically sets forth the core material is encapsulated by a formulation that consists essentially of an animal or vegetable oil. Since the Cuca composition requires a hydrophobic polymer to mask the taste as described above, the particles have to contain the hydrophobic polymer. Cuca does not teach a composition that excludes the hydrophobic polymer, and modifying the composition to not contain a hydrophobic polymer is in contravention to the teachings therein. Since the instant claim uses the

phrases "consists essentially of," the composition cannot include a hydrophobic polymer that Cuca teaches materially effects its composition.

Additionally, claim 102 has been amended to independent form. This amendment should put the claim in appropriate form to overcome the objection that the "consisting essentially of" language in claim 94 does allow for the presence of additional ingredients. Accordingly, since Cuca teaches away from the instantly claimed invention, withdrawal of these rejections is respectfully requested.

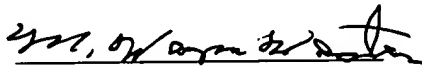
SUMMARY

In view of the foregoing, Applicants believe that claims 51-94, 96-98, 101-105, and 107 present allowable subject matter and allowance is respectfully requested. If any impediment to the allowance of these claims remains after consideration of the above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone Mr. Gary Oakeson, or in his absence the undersigned attorney, at (801) 566-6633, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 4th day of Mar., 2004.

Respectfully submitted,



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